

# Published Regulations and Guidances as of 5-13-15



## FINAL RULES

Title	Pub Date	FR citation
Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents	3/19/2010	75 FR 13225
Amendments to General Regulations of the Food and Drug Administration	11/30/2010	75 FR 73951
Required Warnings for Cigarette Packages and Advertisements	6/22/2011	76 FR 36628
Tobacco Products, Exemptions From Substantial Equivalence Requirements	7/5/2011	76 FR 38961
Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products	2/2/2012	77 FR 5171
Tobacco Products, User Fees, Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products	7/10/2014	79 FR 39302

## PROPOSED RULES

Title	Pub Date	FR citation
Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products	4/14/2011	76 FR 20901
Tobacco Products, Exemptions From Substantial Equivalence Requirements	1/6/2011	76 FR 737
Amendments to General Regulations of the Food and Drug Administration	11/30/2010	75 FR 73984
Required Warnings for Cigarette Packages and Advertisements	11/12/2010	75 FR 69524
Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents	11/17/2011	76 FR 71281
Tobacco Products, User Fees, Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products	5/31/2013	78 FR 32581
National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions	1/23/2014	79 FR 3742

Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products	4/25/2014	79 FR 23142
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## ADVANCE NOTICE OF PROPOSED RULEMAKING

Title	Pub Date	FR citation
Request for Comment on Implementation of the Family Smoking Prevention and Tobacco Control Act	3/19/2010	75 FR 13241
Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products	9/9/2011	76 FR 55835
Menthol in Cigarettes, Tobacco Products; Request for Comments (ANPRM)	7/24/2013	78 FR 44484

## FINAL GUIDANCES

Title	Pub Date	FR citation
Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers	4/25/2011	76 FR 22905
Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act"	1/31/2011	76 FR 5387
Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products	1/6/2011	76 FR 789
Use of "Light," "Mild," "Low," or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products	6/10/2010	75 FR 32953
Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco	6/8/2010	75 FR 32481
Tobacco Health Document Submission	4/20/2010	75 FR 20606
Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco	5/7/2010	75 FR 25271
Timeframe for Submission of Tobacco Health Documents; Availability	12/21/2009	74 FR 67877
General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2)*	12/23/2009	No FR
Listing of Ingredients in Tobacco Products	12/1/2009	74 FR 62795
Registration and Product Listing for Owners and Operators of Domestic Tobacco Product	11/12/2009	74 FR 58298
Small Entity Compliance Guide: Required Warnings for Cigarette Packages and Advertisements; Availability	10/25/2011	76 FR 66074
Small Entity Compliance Guide: Further Amendments to General Regulations of the Food and Drug Administration To Incorporate Tobacco Products; Availability	3/28/2012	77 FR 18830
Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products; Availability	5/25/2012	77 FR 31368

Guidance for Industry on Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents; Availability	8/22/2013	78 FR 52203
Guidance for Tobacco Retailers on Tobacco Retailer Training Programs; Availability	9/5/2013	78 FR 54657
Guidance for Industry and Food and Drug Administration Staff; Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions; Availability	12/4/2013	78 FR 72900
Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments	4/7/2014	No FR
Small Entity Compliance Guide: Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products; Availability	7/16/2014	79 FR 41585
Guidance for Industry and Food and Drug Administration Staff; Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007; Availability	9/29/2014	79 FR 58358
Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions; Guidance for Industry; Availability	3/5/2015	80 FR 12011

## DRAFT GUIDANCES

Title	Pub Date	FR citation
Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments	10/21/2009	74 FR 54052
The Scope of the Prohibition Against Marketing a Tobacco Product in Combination With Another Article or Product Regulated Under the Federal Food, Drug, and Cosmetic Act	10/5/2009	74 FR 51160
Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request	4/25/2011	76 FR 22903
Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents	3/23/2011	76 FR 16424
Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers	8/31/2010	75 FR 53316
Draft Guidance for Tobacco Retailers on Tobacco Retailer Training Programs	7/16/2010	75 FR 41498
'Harmful and Potentially Harmful Constituents' in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act	6/10/2010	75 FR 32952
Compliance With Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents	6/9/2010	75 FR 32791
Tobacco Health Document Submission	12/28/2009	74 FR 68629
Preliminary Timetable for the Review of Applications for Modified Risk Tobacco Products Under the Federal Food, Drug, and Cosmetic Act	11/27/2009	74 FR 62329

Listing of Ingredients in Tobacco Products	11/3/2009	74 FR 56842
Draft Guidance for Industry: Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products; Availability; Agency Information Collection Activities; Proposed Collection	9/9/2011	76 FR 55923
Draft Guidance for Industry and Food and Drug Administration Staff; Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions	9/9/2011	76 FR 55927
Draft Guidance for Industry: Applications for Premarket Review of New Tobacco Products; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request	9/28/2011	76 FR 60055
Draft Guidance for Industry: Modified Risk Tobacco Product Applications; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request	4/3/2012	77 FR 20026
Draft Guidance for Industry: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act; Availability	4/3/2012	77 FR 20030
Draft Guidance for Industry and Food and Drug Administration Staff; Civil Money Penalties for Tobacco Retailers: Responses to Frequently Asked Questions; Availability	2/8/2013	78 FR 9396
Draft Guidance for Industry and Tobacco Retailers; Enforcement Policy for Certain (Provisional) Tobacco Products That the Food and Drug Administration Finds Not Substantially Equivalent; Availability	2/25/2014	79 FR 10534
Draft Guidance for Industry on Substantial Equivalence Reports; Manufacturer Requests for Extensions or To Change the Predicate Tobacco Product; Availability	7/15/2014	79 FR 41292
Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order; Draft Guidance for Tobacco Retailers; Availability	5/13/2015	80 FR 27318